

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>
<b>THIS DOCUMENT RELATES TO:</b>  <b>ALL PLAINTIFFS LISTED IN EXHIBIT A TO PLAINTIFFS' MOTION</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**ETHICON'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS'  
MOTION TO LIMIT THE OPINIONS AND TESTIMONY  
OF PETER L. ROSENBLATT, M.D.**

**INTRODUCTION**

Plaintiffs do not challenge Dr. Rosenblatt's expertise as a pelvic surgeon. *See generally* Plaintiffs' Motion to Exclude [Doc. No. 2425] and Memorandum in Support [Doc. No. 2428]. In fact, they do not discuss his qualifications at all or mention that he is a board-certified urologist with a sub-specialty in Female Pelvic Medicine and Reconstructive Surgery. Ex. A, Rosenblatt Report at 1. He has specialized in minimally invasive surgery to treat pelvic organ prolapse since 1995 and performs approximately 300 surgeries for prolapse and incontinence each year. Rosenblatt Report at 5. He has placed over 2000 slings. Ex. B, Rosenblatt 7/1/16 Dep. Tr. at 113:1-2. He has also taught surgeons across the country and at national conferences regarding the use of mesh devices and has consulted with medical device companies in the development of devices to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). Rosenblatt Report at 2-3. Plaintiffs do not discuss his reliance materials which include a large base of medical literature, including Level 1 evidence such as Cochrane Reviews, meta-analyses

assessing thousands of patients, and numerous randomized controlled trials (RCTs), not to mention public statements by medical societies in the fields of urology. Rosenblatt Report at 4; Reliance List, attached as Ex. C, and Supplemental Reliance List, attached as Ex. D.<sup>1</sup>

Despite Dr. Rosenblatt's years of surgical experience and his review of considerable Level 1 peer-reviewed medical literature and RCTs, the Prolift device IFU, patient brochure and professional education materials, *see, e.g.*, Rosenblatt Report at 38-50, Plaintiffs first seek to preclude Dr. Rosenblatt from testifying about the safety and efficacy of mesh, arguing that his opinions are conjecture and unreliable. Second, Plaintiffs seek to preclude his opinions, based upon his years of experience, that FDA statements and subsequent advertising by plaintiffs' counsel regarding lawsuits over polypropylene mesh products are preventing him from offering his patients the best possible treatment. Third, Plaintiffs attempt to preclude Dr. Rosenblatt from offering testimony that the polypropylene mesh products do not shrink or degrade in the human body. Finally, Plaintiffs attempt to exclude Dr. Rosenblatt's reliance on medical societies' public statements on mesh. None of Plaintiffs' arguments has merit, and their Motion should be denied.

- **Safety and Efficacy:** Dr. Rosenblatt's opinions related to the safety and efficacy of pelvic mesh products is based on his own education, his experience, his extensive review of the literature summarized in his Report, and his reading of professional association statements. He is qualified to give these opinions, and his methodology underlying them is reliable.
- **Attorney Advertising.** Dr. Rosenblatt's opinions regarding the effect of plaintiff's attorney advertising on his clinical practice are not speculative, but rather based on his extensive experience in the use of these products and his clinical practice. Neither are they unduly prejudicial.
- **Physical Properties of Mesh:** This Court has previously rejected attempts to exclude practitioners, like Dr. Rosenblatt, from offering testimony regarding their own

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<sup>1</sup> While Plaintiffs attached Dr. Rosenblatt's Report to their Motion, they did not include his reliance lists or exhibits to that Report.

experiences with Ethicon's products related to the lack of degradation of the products, and should do so again here.

- **Position Statements:** Various medical organizations' position statements on mesh have been previously held admissible by this Court because they are not themselves expert opinions subject to *Daubert*. They provide support for Dr. Rosenblatt's opinions, and the Court should not exclude them in this instance, either.

## **ARGUMENT**

### **I. Standard for admissibility of expert opinion testimony.**

Ethicon incorporates by reference the standard of review for Daubert motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 U.S. Dist. LEXIS 92316, at \*3-8 (S.D. W. Va. July 8, 2014).

### **II. Dr. Rosenblatt's opinions on the safety and efficacy of Gynemesh are well grounded in his extensive training and experience as well as his review of the medical literature.**

Dr. Rosenblatt is a Professor and the Director of Urogynecology and Reconstructive Pelvic Surgery at Mount Auburn Hospital in Cambridge, Massachusetts. Rosenblatt Report at 1. He learned to perform surgeries with transvaginal mesh in the early 1990s. Rosenblatt Report at 11. He has specialized in minimally invasive surgery to treat pelvic organ prolapse since 1995 and performs approximately 300 surgeries for prolapse and incontinence each year. Rosenblatt Report at 5. He has used the TVT starting in 1998 and converted to polypropylene mesh for sacrocolpopexy in the early 2000s. Rosenblatt Report at 12. He began using custom-cut pieces of polypropylene mesh, including Gynemesh PS in the early 2000s for both anterior and posterior prolapse repair. *Id.* He believes that the risks of mesh are well known to pelvic surgeons and that the vast majority of risks associated with mesh also exist with native tissue repairs alone. Rosenblatt Report at 19-21. He believes that there is a benefit to using mesh over native tissue repair; namely, that although there is a chance of mesh exposure with that procedure, there is a significantly higher rate of recurrent prolapse with native tissue repair,

potentially requiring complicated re-operation for the prolapse. Rosenblatt Report at 21. He cited numerous studies in his expert report supporting his opinions that Gynemesh and Prolift are safe and effective. Rosenblatt Report at 38-42. Additionally, Dr. Rosenblatt has had experience in design of mesh products. 7/1/16 Rosenblatt Dep. Tr. 164:17-165:18. He had worked with engineers, companies, and independently on some of his own products. *Id.* For example, he has worked with a company in Rhode Island called Biomedical Structures on some of his own mesh designs, and a mesh manufacturer in Ireland called Proxy Medical that makes mesh for companies in the United States, including Boston Scientific. *Id.*

Dr. Rosenblatt's opinions related to the safety and efficacy issues are based not only in his personal education and clinical experience, but also in Level 1 evidence such as Cochrane Review, meta-analyses assessing thousands of patients, and numerous randomized controlled trials (RCTs), not to mention public statements by medical societies in the fields of urology. Rosenblatt Report at 4, 19-48; Reliance Lists, attached as Exs. C & D. Notably, Plaintiffs do not challenge the vast majority of Dr. Rosenblatt's opinions.

**A. Plaintiffs offer no reason to exclude Dr. Rosenblatt's testimony on safety and efficacy based upon the number of surgeries he performed.**

Plaintiff seeks to exclude Dr. Rosenblatt's opinions on the safety and efficacy of Gynemesh PS and Prolift as "mere conjecture" because he testified that he is "still using TVT-O, and occasionally Gynemesh" and does not currently use Prolift. Plaintiffs' Memorandum at 4-5. Their argument with respect to Prolift is a red herring: Ethicon decommercialized Prolift in 2012. Dr. Rosenblatt's deposition was taken in July 2016. Dr. Rosenblatt obviously cannot use a device that has been off the market for four years. Moreover, although Gynemesh is still available, it is currently indicated for only abdominal use. As Dr. Rosenblatt himself testified, "[O]ver the last couple years, Ethicon has dropped their sales force and there are rumors that

they may stop manufacturing altogether. So I wanted to get prepared for that day, and so I started looking at other sling products . . . [and] have transitioned myself slowly to Boston Scientific.” 7/1/16 Rosenblatt Dep. Tr. 49:9-22.

The fact is that Dr. Rosenblatt has been familiar with mesh since the early 1990s and has been using Gynemesh since the early 2000s. Rosenblatt Report at 12. He performs approximately 300 surgeries for POP and SUI per year. *Id.*; Rosenblatt 7/1/16 Dep. Tr. 113:1-2. Despite this extensive experience, including approximately 15 years of familiarity with Gynemesh, Plaintiffs make the puzzling argument that simply because Dr. Rosenblatt only occasionally uses Gynemesh or Ethicon products currently, that his opinions are not based on “sound methodology.” Plaintiffs’ Memorandum at 5. This argument simply does not make sense. First, Gynemesh PS is the same mesh that is used in Prolift. The only difference is that Gynemesh PS is a flat sheet of mesh that the surgeon cuts by hand, whereas Prolift consists of a pre-cut shape of Gynemesh PS. Dr. Rosenblatt explains the evolution of pre-cut mesh products in his report. *See* Rosenblatt Report at 13.

Second, Dr. Rosenblatt’s methodology for determining his opinions on safety and efficacy is based upon his long experience using Gynemesh products, as well as his extensive review of the literature—indeed, Plaintiffs cite no law for the proposition that simply because the proposed expert has used the defendant’s products less frequently in the immediately preceding year, that that expert’s long history and familiarity with that product is somehow negated.

Only three years ago, Dr. Rosenblatt used Ethicon’s products in 100% of sling procedures he performed. *Id.* at 50:6-12. Notably, Dr. Rosenblatt did not cite any issues with Ethicon’s products as a reason for his less-frequent use of them. The Court should deny

Plaintiffs' bare-bones, unsupported argument that Dr. Rosenblatt's frequency of use of Gynemesh products somehow detracts from his ability to opine as to their safety and efficacy.

**B. Dr. Rosenblatt's opinions regarding exposure do not provide a basis for excluding his opinions regarding safety and efficacy.**

Dr. Rosenblatt acknowledges that exposure is a risk of mesh surgery. Rosenblatt Report at 21; 7/1/16 Dep. Tr. 38:6-39:11. Plaintiffs argue that Dr. Rosenblatt's opinions that the "Gynemesh PS used in Prolift is not defective just because a small percentage of patients might experience mesh exposures or other well-known and acceptable complications" should be excluded because, when asked in his deposition what percentage of Prolift patients would have to experience mesh exposures for him to consider Prolift defective, Dr. Rosenblatt testified that he did not think there was a specific number. Plaintiffs' Memorandum at 5-6. Plaintiffs claim that simply because Dr. Rosenblatt did not cite a specific percentage that his opinion is unreliable. *Id.* This argument misses the point: Dr. Rosenblatt did *not* testify that his opinion was controlled by a specific percentage; rather, he testified that different exposure rates "ha[ve] to do with techniques, surgeon techniques, as well as . . . the factors associated with the patient[,] like age and estrogenization and menopausal status, obesity, comorbidities like diabetes." Rosenblatt 7/1/16 Dep. Tr. 60:17-24; *see also id.* 163:4-13 (testifying that factors unrelated to the mesh itself contribute to mesh exposure).

He reaffirmed his opinion in his deposition that "a specific percentage [of patients who experience exposure] does not denote a defect in the product itself," because the factors that are controlling for Dr. Rosenblatt are surgical technique and clinical factors. Rosenblatt 7/1/16 Dep. Tr. 60:22-24. The specific percentage of patients who experience exposure is simply not part of Dr. Rosenblatt's methodology, and Plaintiffs have cited no evidence demonstrating that it should be. However, any claimed lack of support (which Ethicon disputes), does not detract from his

opinions. *Cf. Winebarger v. Bos. Sci. Corp.*, No. 2:13-cv-28892, 2015 WL 1887222, at \*34 (S.D. W. Va. Apr. 24, 2015) (expert's inability to provide "exact statistics" about the outcome of his patients did not render his personal experience opinions unreliable as "such detail is not required under *Daubert* to opine as to 'large-scale safety and efficacy of the [ ] device.'"). Any asserted failure in his analysis is better addressed on cross examination than by excluding the testimony. This is especially true where Dr. Rosenblatt relies extensively on high level and scientifically reliable medical studies and literature to support his conclusions as set forth in his Report, and not simply on rough factors discussed during his deposition.

Plaintiffs further suggest that the "analytical gap" is too great regarding Dr. Rosenblatt's opinion that Prolift is not defective and his testimony that he could not note a single percentage that would automatically deem Prolift to be defective. Plaintiffs' Memorandum at 6. Plaintiffs assume that Dr. Rosenblatt, who volunteered that he is aware of studies with exposure rates as high as 20% (and as low as 5% or 2%), is ignoring studies that show high rates of exposure without explaining why he did not take them into account. *Id.* But Plaintiffs failed to ask him about any of the specific studies he referenced in his Prolift report, *see* Rosenblatt Report at 32-42, and instead, used the entirety of their deposition time to question Dr. Rosenblatt about TVT.

As discussed above, Dr. Rosenblatt's report and reliance list provide a sound basis for his opinion that Prolift is not defective. For example, Dr. Rosenblatt extensively discusses that "Mesh Exposure and Erosion Are Well Known Risks," from pages 42-45 of his report. His opinion that mesh is not necessarily defective is based upon the fact that there are other risk factors for mesh exposure, such as those described on page 42 of his report: "Known risk factors for mesh exposure or erosion include: estrogen deficiency, improper dissection planes, poor tissue integrity, post-hysterectomy 'T' scar, subclinical infection, hematoma formation, increased

mesh area (“mesh load”), and lack of integration of the mesh into the host tissue. [Kobashi, Sci World J 2009].” Rosenblatt Report at 42.

**C. Dr. Rosenblatt’s opinion that mesh has been successful for millions of women is well-supported and reliable.**

Plaintiffs next argue that Dr. Rosenblatt’s opinion that “mesh” has been successful in “millions of women” is a “nebulous” and “completely unreliable” opinion. Plaintiffs’ Memorandum at 8. The problem with this argument, however, is that Plaintiffs’ counsel phrased the question referring to “polypropylene,” not any one specific product. *See* Rosenblatt 7/1/16 Dep. Tr. 87:13-88:6 (“Q. If there was credible scientific evidence that polypropylene is cytotoxic, would that render it not suitable for permanent implants in women? A. No, I think it would have to have some clinical significance. And again, let’s go back and state, as I did earlier, that we’ve been using polypropylene and Prolene sutures for decades, and I’m not aware of any untoward effects that might have any clinical significance . . . . you’ve got several million women that have benefited greatly from this technology over a period of, you know, over 17 years . . . .”). This global reference to “polypropylene” would, in essence, cover polypropylene sutures, polypropylene hernia meshes, polypropylene midurethral slings (*i.e.*, TVT), polypropylene sacrocolpopexy meshes, and polypropylene pelvic organ prolapse meshes (Gynemesh PS/Prolift). One need only look at the position statements, *see infra*, to see how polypropylene midurethral slings have benefitted millions of women.

Plaintiffs further erroneously argue that Dr. Rosenblatt “does not point to any study finding that millions of women have benefitted from mesh,” when in actuality, Dr. Rosenblatt has cited and considered the 2013 AUGS-SUFU position statement on pages 30-31 of his report. That position statement concluded that

[t]he polypropylene midurethral sling has helped *millions of women* with SUI regain control of their lives by undergoing a

simple outpatient procedure that allows them to return to daily life very quickly. With its acknowledged safety and efficacy, it has created an environment for a much larger number of women to have access to treatment. In the past, concerns over failure and invasiveness of surgery caused a substantial percentage of incontinent women to live without treatment. One of the unintended consequences of this polypropylene mesh controversy has been to keep women from receiving any treatment for SUI. This procedure is probably the most important advancement in the treatment of stress urinary incontinence in the last 50 years and has the full support of our organizations which are dedicated to improving the lives of women with urinary incontinence.

*See* Ex. E, AUGS-SUFU 2013 Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence at 3 (emphasis added). Plaintiffs' argument has no merit and should be disregarded.

**III. Dr. Rosenblatt's Opinions Regarding the Effect of Attorney Advertising on His Ability to Offer His Patients the "Best Treatment Possible" are Based on his Clinical Experience and are Admissible.**

In his report, Dr. Rosenblatt discusses the FDA's 2008 Public Health Notification and 2011 Safety Update, which stated that complications from the use of transvaginal mesh are "not rare." Rosenblatt Report at 13-14. Dr. Rosenblatt's opinion is that this statement by the FDA has opened the door to tens of thousands of lawsuits against medical device manufacturers of transvaginal mesh products. Rosenblatt Report at 15. In his deposition, Dr. Rosenblatt elaborated on his concerns regarding the influx of lawsuits against device manufacturers, stating that he believed that advertising for such lawsuits have done a "real disservice" to women. Rosenblatt 7/1/16 Dep. Tr. 45:8-11. He bases this testimony on his personal experience of speaking with patients who tell him that, due to this advertising, they are afraid to have mesh implants and prefer alternatives such as Burch procedures. Rosenblatt 7/1/16 Dep. Tr. 90:2-91:18. This hampers Dr. Rosenblatt's ability to "take care of [his] patients and to offer them the best treatment possible." Rosenblatt 7/1/16 Dep. Tr. 91:25-92:1.

Plaintiffs opened the door to this testimony by questioning Dr. Rosenblatt regarding the fact that he is currently performing more Burch procedures in his practice, and by implying that that this increase was due to complications related to polypropylene mesh. Rosenblatt 7/1/16 Dep. Tr. 91:8-11. Dr. Rosenblatt was entitled to explain why his practice has changed, and to correct Plaintiffs' false implication. As he testified, although he has recently experienced an increase in the number of Burch procedures he performs for SUI,<sup>2</sup> that increase is attributed to misinformation and fear mongering. Rosenblatt 7/1/16 Dep. Tr. 90:2-92:10. Dr. Rosenblatt expressed his opinion that women are being taken advantage of by medical lenders who "lend[] patients money and jack[] up the bills artificially so that when women get their settlements most of the settlement money" does not actually go to the women who have been injured. Rosenblatt 7/1/16 Dep. Tr. 45:12-46:5.

Plaintiffs argue that his opinions should be excluded because they are based on speculation and belief. Plaintiffs' Memorandum at 11. This could not be further from the case; Dr. Rosenblatt clearly testifies from his extensive experience treating real-world patients and seeing their real-world hesitancy to accept a procedure that Dr. Rosenblatt, in his professional medical judgment, believes is the best treatment possible for their condition. Dr. Rosenblatt has never opined that mesh is appropriate for every woman. *See* Rosenblatt Report at 6-12 (discussing different treatment options for women with POP). Dr. Rosenblatt is qualified to opine on the reasons women tell him that they decline mesh based on his knowledge, experience, and training. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 726 (S.D. W. Va. 2014) (allowing expert testimony based on observations in clinical practice).

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<sup>2</sup> Although Dr. Rosenblatt's opinions concern Prolift and Prolift+M, Plaintiffs' counsel questioned Dr. Rosenblatt predominantly regarding his opinions on TVT, which is used to treat SUI, in his deposition.

In accordance with this Court's previous rulings and guidance, Dr. Rosenblatt does not intend to offer opinions regarding the FDA itself. But Dr. Rosenblatt's criticisms regarding misleading or overstated advertising regarding mesh complications and his concerns regarding his patients are not without support. Dr. Rosenblatt cites several randomized controlled trials referenced by the FDA comparing transvaginal mesh to traditional surgery, for which the primary outcome of most is anatomic cure. *See* Rosenblatt Report at 16-17; *see also* Rosenblatt 7/1/16 Dep. Tr. 44:2-24. He also supports his opinions with an article entitled "Time to rethink: an evidence-based response from pelvic surgeons to the FDA Safety Communication: 'UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse,'" which is attached hereto as Ex. F. Rosenblatt Report at 18. Additionally, Dr. Rosenblatt's opinion that medical lenders are taking advantage of women by lending them money is supported by a Reuters article<sup>3</sup> cited by Dr. Rosenblatt at his deposition. Rosenblatt 7/1/16 Dep. Tr. 45:12-46:5. The Reuters article features a urogynecologist named Dr. Andrew Cassidenti, who Dr. Rosenblatt testified was a colleague of his and with whom he has spoken regarding medical lenders contacting Dr. Cassidenti and asking him to remove mesh from women for money. Rosenblatt 7/1/16 Dep. Tr. 46:6-13. Dr. Rosenblatt's opinions are relevant to his opinions regarding the safety of the polypropylene mesh, are relevant to explaining why his use of the Burch procedure has increased, are well-supported by literature and experience and should not be excluded.

#### **IV. Dr. Rosenblatt's Degradation Opinions are Well-Supported and Proper.**

Dr. Rosenblatt has over twenty years of surgical experience. Rosenblatt Report at 22. He performs approximately 300 surgeries for POP and SUI each year and has placed over 2000

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<sup>3</sup> That article is available online at <http://www.reuters.com/investigates/special-report/usa-litigation-mesh/>.

slings. Rosenblatt 7/1/16 Dep. Tr. 113:1-2. Dr. Rosenblatt testified in his deposition that, in the past, he has removed Prolene mesh before and has “not seen any degradation of the mesh.” Rosenblatt 7/1/16 Dep. Tr. 84:6-14; *see also id.* 110:7-16 (“[W]e have literally half a century or more of data and clinical experience with Prolene. So I’m very comfortable that it doesn’t degrade.”). He also cited medical literature failing to find degradation in mesh. Rosenblatt 7/1/16 Dep. Tr. 173:18-174:11. He noted that he has “searched the medical literature and [has] not seen any reliable scientific literature that establishes any clinical significance to the debated surface cracking that has been under powerful scanning electron microscopy.” *Id.*; *see also id.* 168:19-171:7 (citing multiple studies finding no shrinkage in mesh).

This Court has previously permitted pelvic surgeons to testify regarding their personal clinical experience related to the lack of degradation of pelvic mesh products. *Huskey*, 29 F. Supp. 3d at 726-27. This Court recently reiterated its conclusion that an expert’s reliance on a lack of scientific articles demonstrating degradation of mesh, combined with clinical experience constitutes reliable, scientific methodology to offer an opinion concerning degradation of polypropylene mesh. *Huskey*, 29 F. Supp. 3d at 734-35. Dr. Rosenblatt seeks to do the same here.

Dr. Rosenblatt’s opinion is that there is no scientific evidence that mesh does not shrink. Plaintiffs claim that Dr. Rosenblatt contradicted this opinion in his deposition when he acknowledged a study by Uwe Klinge and Bernd Klosterhalfen purporting to find that mesh does shrink. Plaintiffs’ Memorandum at 12-14. Dr. Rosenblatt is qualified by education, training and experience to offer the opinion that polypropylene mesh does not shrink or degrade. Dr. Rosenblatt’s opinion is further supported by the literature and studies he cited that support his position. Rosenblatt Report at 21-22.

He further relies on his extensive twenty-plus years of surgery for his opinion that polypropylene mesh does not shrink. Rather, he opines that scar tissue, which can occur after surgery of any kind, may contract; not mesh. *Id.* at 22. His report is consistent with his deposition testimony:

A. . . . I don't believe that mesh shrinks, and mesh does not shrink. There's no such thing as mesh shrinking. It's not like you put it in a dryer like, you know, a shirt in a dryer and it gets smaller. *It's the fibrosis that occurs as a natural healing process of surgery that causes shrinkage.* . . . Mesh does not shrink. So if there is any decrease in the surface area of the mesh, it's not from the mesh itself. *It's the tissue around the mesh.*

Rosenblatt 7/1/16 Dep. Tr. 117:1-15. *See Wise v. C.R. Bard, Inc.*, 2015 WL 521202, at \*20 (S.D. W. Va. Feb. 7, 2015) (discussing different interpretations of “mesh shrinkage”).

According to Dr. Rosenblatt, “[t]here’s no contractile elements within a mesh” that could shrink. Rosenblatt 7/1/16 Dep. Tr. 116:8-9. Rather, the body’s reaction to surgery “could react around a mesh to contract,” and even native tissue repairs carry the risk of vaginal foreshortening. *Id.* 116:9-12. But, based on his experience with “hundreds and hundreds of transvaginal meshes,” there is no clinically significant shrinkage associated with correctly placed mesh. *Id.* 116:15-19. He evaluated reams of medical literature: “I didn’t cherry pick to say, okay, that article supports my theory and that’s all I’m going to look at. I looked at it all.” Rosenblatt 7/1/16 Dep. Tr. 120:21-22. Plaintiffs notably omit this testimony.

Plaintiffs confuse Dr. Rosenblatt’s opinion that mesh itself does not shrink with some of the animal studies conducted by Klinge and Klosterhalfen that refer to “mesh shrinkage.” They argue that because these animal studies exist that are purportedly contrary to his opinions, then his opinions must be excluded. Plaintiffs’ Memorandum at 14. Dr. Rosenblatt admits such animal studies exist. He just finds them unpersuasive in light of his vast experience and

literature showing no shrinkage in humans to the contrary.<sup>4</sup> Rosenblatt 7/1/16 Dep. Tr. 116:2-117:15. Further, the existence of claimed contrary studies is fodder for cross examination, not a basis to exclude Dr. Rosenblatt's opinions as unreliable when they are based both on his considerable personal experience as well as medical literature and studies. *See Carroll v. Boston Scientific Corp.*, Civ. A. No. 2:13-cv-11601, 2016 U.S. Dist. LEXIS 60335, at \*10-11 (S.D.W. Va. May 6, 2016) (expert's failure to consider document goes to weight, not admissibility, of opinion testimony); *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) ("the court need not determine that the expert testimony a litigant seeks to offer into evidence is irrefutable or certainly correct.").

As to Plaintiffs' argument that Dr. Rosenblatt did not personally conduct tests, look at polypropylene mesh pore size under a microscope, or ask pathologists to examine his explants for inflammation or foreign body response, such personal testing is not a prerequisite to admissibility, as this Court found in *Huskey*. 29 F. Supp. 3d at 706-07. *See* Plaintiffs' Memorandum at 15. Here, Dr. Rosenblatt's opinions are the result of his extensive education, training, experience and appropriate reliance upon applicable medical literature. *See, e.g.*, Rosenblatt 7/1/16 Dep. Tr. 66:8-25 (opining, based on his experience "on countless cases" that the pores in Prolene mesh are not too small because Prolene mesh is a macroporous Type 1 monofilament material that undergoes excellent integration into patients' tissues"); *id.* at 78:1-19 (opining that he has "never seen any literature or in my personal experience doing this for . . . 20 years that any kind of response to a foreign material translates into a clinically significant

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<sup>4</sup> Indeed, some of Klinge and Klosterhalfen's own studies confirm this opinion. *See* Ex. G, "The lightweight and large porous mesh concept for hernia repair," at 8 (stating, at Figure 5(A), that it shows "mesh shrinkage after long-term implantation," but that "it is not the mesh itself undergoing the process of shrinkage, the phenomenon is a result of contracting scar tissues around the mesh").

problem”); *id.* at 182:25-184:22 (testifying to a 2015 study by Audra Jolyn Hill in the International Urogynecology Journal that supported his opinion that a chronic inflammatory response is not indicative or causally related to chronic pain). These opinions are well-supported and need not be accompanied by his personal testing.

**V. Dr. Rosenblatt Properly Relies on Physician Organization Statements and Guidelines Promoting the Safety and Efficacy of the TVT.**

Plaintiffs finally argue that Dr. Rosenblatt should be prohibited from referencing the statements of various physician trade associations or organizations, such as the American Urogynecologic Society (“AUGS”). In his report, Dr. Rosenblatt extensively discusses the position statements of various organizations and associations, which recommend vaginal mesh as efficacious and/or preferred in certain circumstances (Rosenblatt Report at 27-32). In particular, in 2013, two organizations published a position statement on mesh mid-urethral slings for SUI, stating that they were the “worldwide standard of care for the surgical treatment of stress urinary incontinence.” *Id.* at 30. These positions statements support and confirm Dr. Rosenblatt’s opinions. *Id.* at 32.

The position statements have never been excluded in any trial to date. This Court has previously reserved ruling on the positions statements in prior *Daubert* orders. *See, e.g., Huskey v. Ethicon, Inc.*, No. 2:12-cv-5201, Order on Daubert Motions, Dkt. 271, at Page 56-57 (declining to rule on expert’s reference to position statements because they themselves are not expert opinions subject to Rule 702); *Eghnayem v. Ethicon, Inc.*, No. 2:13-cv-07965, 2014 U.S. Dist. LEXIS 152457, at \*142-43 (same) (S.D. W. Va. Oct. 27, 2014). In rulings on motions in limine, the Court has suggested that position statements are admissible because (1) they might be relied upon by experts under the learned treatise exception to the hearsay rule; (2) experts are permitted to rely on otherwise inadmissible information provided that they would reasonably rely

on those kinds of facts or data in forming an opinion on the subject; and (3) they may be out-of-court statements offered to show Ethicon's state of mind for purposes of the punitive damages claims. *See Huskey v. Ethicon, Inc.*, No. 2:12-cv-5201, 2014 U.S. Dist. LEXIS 107887, at \*7 (S.D. W. Va. Aug. 6, 2014); *see also* Ex. H, *Huskey v. Ethicon Inc.*, No. 2:12-cv-5201, Trial Tr. 9/3/14, at 121:2-124:24 (allowing Dr. Pramudji to testify regarding position statements and whether she agreed with them).

Plaintiffs argue conclusorily that because this Court has previously noted that position statements are not expert opinions, they should be excluded in their entirety. Plaintiffs' Memorandum at 16. Plaintiffs' argument is not well taken. It does not follow that because position statements are not expert opinions they should be excluded. Rather, as this Court has observed, the position statements may properly form the basis for an expert's opinion. *See Huskey*, 2014 U.S. Dist. LEXIS 107887, at \*7.

Ethicon's experts and physicians in the field rely on position statements. Dr. Rosenblatt may therefore explain to the jury that the statements of these organizations support his opinions that use of the device is recommended and beneficial in certain circumstances.

### CONCLUSION

For the reasons set forth above, the Court should deny Plaintiffs' Motion to Exclude Certain Opinions of Peter Rosenblatt, M.D.

This the 8<sup>th</sup> day of August, 2016.

Respectfully submitted,

ETHICON, INC. AND  
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### **CERTIFICATE OF SERVICE**

I certify that on August 8, 2016, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones

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